K120148

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AOS

ADVANCED ORTHOPAEDIC SOLUTIONS

5. TRADITIONAL 510(K) SUMMARY

OCT 2 2012

DATE PREPARED: October 1, 2012

SUBMITTED BY:
Advanced Orthopaedic Solutions, Inc.
386 Beech Avenue, Unit B6
Torrance, CA 90501
Phone: (310) 533-9966

CONTACT PERSON:
Julie Glendrange
Advanced Orthopaedic Solutions, Inc.
386 Beech Avenue, Unit B6
Torrance, CA 90501
Phone: (310) 533-9966

DEVICE NAME: AOS Trochanteric Nail System, Telescoping (TC^{II}) Lag Screw and Solid Locking Lag Screw

COMMON NAME: Internal Fixation

CLASSIFICATION: Class II, 21 CFR 888.3020 Rod, Fixation, Intramedullary and Accessories

DEVICE CODE: HSB

SUBSTANTIALLY EQUIVALENT DEVICE: AOS Trochanteric Nail System (510(k): K021008, Cleared June 20, 2002 and K103533, Cleared Jan. 19, 2011); and
EBI® Trochanteric Nail System (510(k): K050118, Cleared Feb. 16, 2005)

DEVICE DESCRIPTION: The AOS Solid Locking and Telescoping Lag Screws are used in the AOS Trochanteric Nail System, in conjunction with the AOS Trochanteric Nail. Both AOS screws can be locked to the nail. The Telescoping Lag Screw allows the threads to collapse within the barrel.

INDICATIONS FOR USE: The AOS Trochanteric Nail is intended to treat stable and unstable proximal fractures of the femur including pertrochanteric, intertrochanteric and high subtrochanteric fractures and combinations of these fractures. The long trochanteric nail is additionally indicated for subtrochanteric fractures, pertrochanteric fractures associated with shaft fractures, pathologic fractures (including prophylactic

use) in osteoporotic bone of the trochanteric and diaphyseal areas, long subtrochanteric fracture, ipsilateral femoral fractures, proximal and distal non-unions and malunions and revisions procedures.

SUBSTANTIAL EQUIVALENCE: Information presented supports substantial equivalence of the AOS Solid Locking and Telescoping Lag Screws to the predicate devices. The proposed systems have the same indications for use, are similar in shape and design, have the same fundamental technology and are made of the same material.

PRECLINICAL TESTING: The AOS Solid Locking and Telescoping Lag Screws were each subjected to static and fatigue testing in accordance with ASTM F384, Standard Specifications and Test Methods for Metallic Angled Orthopedic Fracture Fixation Devices. The results demonstrate that the Solid Locking and Telescoping Lag Screws are substantially equivalent to the predicate devices. Additionally, the Telescoping Lag Screw was subjected to torque testing in accordance with ASTM F543, Standard Specifications and Test Methods for Metallic Medical Bone Screws.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 2 2012

Advanced Orthopaedic Solutions, Inc.
% Ms. Julie Glendrange
386 Beech Avenue, Unit B6
Torrance, CA 90501

Re: K120148
Trade/Device Name: Solid Locking Lag Screw and TCII - Telescoping Lag Screw
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: September 14, 2012
Received: September 17, 2012

Dear Ms. Glendrange:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the [kit/tray] have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin L. Keith

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

AOS

ADVANCED ORTHOPAEDIC SOLUTIONS

4. INDICATIONS FOR USE STATEMENT

Traditional 510(k) Premarket Notification
Indications for Use Statement
AOS Trochanteric Nail System

510(k) Number (if known): K120148

Device Name: AOS Trochanteric Nail System

Indications for Use:

The AOS Trochanteric Nail is intended to treat stable and unstable proximal fractures of the femur including pertrochanteric, intertrochanteric and high subtrochanteric fractures and combinations of these fractures. The long trochanteric nail is additionally indicated for subtrochanteric fractures, pertrochanteric fractures associated with shaft fractures, pathologic fractures (including prophylactic use) in osteoporotic bone of the trochanteric and diaphyseal areas, long subtrochanteric fracture, ipsilateral femoral fractures, proximal and distal non-unions and malunions and revisions procedures.

Prescription Use: X AND/OR Over-The-Counter Use: ____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120148